

CLAIMS

1-70. (cancelled).

71-76. (cancelled).

77. (currently amended) A controlled release methylphenidate tablet ~~as defined in claim 71~~ consisting of:

(A) an immediate release methylphenidate coating consisting ~~essentially~~ of;

- (a) 30-60 weight percent based upon the total weight of the immediate release coating of methylphenidate or a pharmaceutically acceptable salt or isomer thereof;
- (b) 40-70 weight percent based upon the total weight of the immediate release coating of a binder; and
- (c) 0.005-5 weight percent based upon the total weight of the immediate release coating of a stabilizer;

(B) a controlled release methylphenidate core tablet consisting of:

(a) a compressed mixture consisting ~~essentially~~ of:

- (i) 5-40 weight percent based upon the total weight of the compressed mixture of methylphenidate or a pharmaceutically acceptable salt or isomer thereof;
- (ii) 3-40 weight percent based upon the total weight of the compressed mixture of a hydrogel polymer;
- (iii) 25-90 weight percent based upon the total weight of the compressed mixture of a diluent; and
- (iv) ~~0.1-10 weight percent based upon the total weight of the compressed mixture of a~~ optionally a lubricant; and

(b) an enteric coating surrounding the core tablet consisting ~~essentially~~ of;

- (i) 45-80 weight percent based upon the total weight of the enteric coating of a combination of enteric polymers consisting of zein and at least one additional enteric polymer selected from the group consisting of methacrylic acid copolymers, cellulose acetate phthalate, hydroxypropyl methylcellulose phthalate,

hydroxypropyl methylcellulose acetate succinate, cellulose acetate trimellitate, shellac, polyvinyl acetate phthalate or mixtures thereof ~~at least one enteric polymer;~~

(ii) 0.5-15 weight percent based upon the total weight of the enteric coating of a plasticizer;

(iii) an anti-sticking agent; and

(iv) ~~optionally~~ a surfactant; and

(C) optionally an aesthetic coating;

wherein the controlled release methylphenidate tablet exhibits the following dissolution profile when tested in a United States Pharmacopeia type 2 (paddle) apparatus at 50 rpms in 900 ml of phosphate buffer with a pH of 7.5 and at 37°C:

1-35% of the methylphenidate is released after 1 hour;

5-40% of the methylphenidate is released after 2 hours; and

not less than 70% is release after 10 hours; and

when administered to humans exhibits a plasma peak for the immediate release layer (T_{max1}) between 1 and 5 hours, a plasma peak for the controlled release core (T_{max2}) between 4 and 12 hours, and a plasma trough (T_{min}) between 2 and 7 hours in between the two peak plasma levels; and wherein the immediate release methylphenidate coating (A) is applied to the enteric coating surrounding the core tablet.

78. (currently amended) The controlled release methylphenidate tablet as defined in claim ~~74~~ 77 wherein:

(A) the immediate release methylphenidate coating consists of;

(a) 40-50 weight percent based upon the total weight of the immediate release coating of methylphenidate or a pharmaceutically acceptable salt or isomer thereof ;

(b) 45-60 weight percent based upon the total weight of the immediate release coating of a binder; and

(c) 0.01-2 weight percent based upon the total weight of the immediate release coating of a stabilizer;

(B) the controlled release methylphenidate core tablet consists of:

- (a) a compressed mixture consisting of:
 - (i) 10-25 weight percent based upon the total weight of the compressed mixture of methylphenidate or a pharmaceutically acceptable salt or isomer thereof;
 - (ii) 3-40 weight percent based upon the total weight of the compressed mixture of a hydrogel polymer;
 - (iii) 45-85 weight percent based upon the total weight of the compressed mixture of a diluent; and
 - (iv) ~~0.5-5~~ 0.1-10 weight percent based upon the total weight of the compressed mixture of a lubricant; and
- (b) an enteric coating surrounding the core tablet consisting of;
 - (i) 45-80 weight percent based upon the total weight of the enteric coating of ~~at least one~~ the combination of enteric polymers;
 - (ii) 1-5 weight percent based upon the total weight of the enteric coating of a plasticizer;
 - (iii) an anti-sticking agent; and
 - (iv) optionally a surfactant.

79. (cancelled).

80. (currently amended) The controlled release tablet of claim ~~79~~ 77 wherein the at least one additional enteric polymer is a methacrylic acid copolymer.

81-83. (cancelled).

84. (currently amended) The controlled release methylphenidate tablet as defined in claim ~~81~~ 80 wherein the T_{max2} occurs about 7 to 9 hours and declines to about 1.4 ng/ml in about 14 to 18 hours.

85. (new) The controlled release methylphenidate tablet of claim 78 wherein the compressed mixture of the core tablet consists of 0.5-5 weight percent based upon the total weight of the compressed mixture of a lubricant.